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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,615	06/26/2001	Gregory Plowman	038602-1214	8543

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EXAMINER	
BORIN, MICHAEL L	
ART UNIT	**PAPER NUMBER**
1631	10

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/888,615	Applicant(s) Plowman et al.
	Examiner Michael Borin	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____

2a)☐ This action is **FINAL.** 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-30 are subject to restriction and/or election requirement

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examine

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Part III DETAILED ACTION

Claims 1-30 are currently pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5,24-26, drawn to polynucleotides encoding full-length polypeptides, analogs and fragments thereof, and vectors and transformed host cells, classified in class 536, subclass 23.1.

II. Claims 6-8, drawn to a purified polypeptide, classified in class 530, subclass 300.

III. Claims 9-11, drawn to an antibody to a polypeptide, classified in class 530, subclass 388.1.

IV. Claim 12, drawn to method of screening based on interaction with polypeptide, classified in class 435, subclass 7.1

V. Claim 13, drawn to method of screening based on expression of polypeptide, classified in class 435, subclass 7.1.

VI. Claims 14-19, drawn to method of treatment using polypeptide, classified in class 514, subclass 12.

VII. Claim 20-23, drawn to polynucleotide-based methods of screening, classified

in class 435, subclass 6.

VIII. Claims 27-29 drawn to 10-30 long oligonucleotides, classified in class 536, subclass 23.1.

IX. Claims 9-11, drawn method of use of antibodies, classified in class 435 subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group II, the critical feature is a polypeptide whereas for Group I the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group II to be directed as to its synthesis by a polynucleotide of Group I, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from

being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Groups I and VIII are drawn to full-length polynucleotides encoding polypeptides and short oligonucleotide fragment,respectively. There is no common core structure for the polynucleotides as claimed. Accordingly, a reference teaching, e.g., a polynucleotide comprising a 10-mer from a certain parent polynucleotide, will not teach or suggest the full-length polynucleotide. Therefore, each group requires non co-extensive sequence and literature searches. Further, inventions are drawn to independent and/or patentably distinct polynucleotides since each would be expected to possess distinctly different structure, and/or physico-chemical properties, and/or capable of separate manufacture and/or use.

Inventions I and III are separate and distinct, as the claims of Invention I are drawn to polynucleotides, while the claim of group III is drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention III would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

Inventions II and III are separate and distinct as the polypeptides of Invention

II are structurally and biochemically different than the antibodies of Invention III. While the antibodies may bind to the polypeptides of Invention II, the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner.

Inventions I and VII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, product of Group I can be used in a different process, e.g., production of peptides.

Inventions II and IV-VI are related as product and processes of use. Methods IV-VI are alternate methods of using the compound of Group I, and the polypeptides of Group II can be used in other methods, e.g., production of antibodies.

Inventions IV-VI are related as independent methods of use of polypeptides, which are not connected in design, operation or effect. The methods have different effects, functions and/or modes of operation, and are not disclosed as as capable of use together.

Inventions III and IX are related as product and process of use. Product of

Group I can be used in a different process, e.g., stimulation of immune response.

Inventions IV-VI and VII are related as independent methods of use as they use different products.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on a plurality of independent and/or patentably distinct sequences. Each peptide or nucleic acid sequence is independent and/or patentably distinct because they are unrelated compounds, there is no disclosed core structure required for a common utility, and because each of these compounds possess different structure and/or physico-chemical properties, and/or capable of separate manufacture and/or use. **For an elected Group the Applicants must further elect a single amino acid or nucleic acid sequence.**

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Examination will be restricted only to a Group drawn to elected sequences.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, and the necessity for non-coextensive literature searches restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Species Requirement

Election of species should be required prior to a search on the merits in all applications containing both species claims and generic or Markush claims.(MPEP 808.01(a))

If Group I is elected, the following election of species is hereby required for the initial search for examination on merits:

The claims of the Group are generic to a plurality of disclosed patentably distinct species of polynucleotides which encode i) a full-length polypeptide (as in claim 1); ii) biological domain of a polypeptide (as in claim 24), and iii) different polypeptides that are >90% identical to said polypeptide. The species encompass different compound species that require a burdensome classification, and/or bibliographic, manual and computer search.

Accordingly, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though the requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the

other invention.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Mr. Michael Woodward, can be reached at (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 26, 2003

MICHAEL BORIN, PH.D
PRIMARY EXAMINER